

Over-the-Counter Monograph User Fee Program Performance Goals and Procedures - Fiscal Years 2021-2025

| Activity | Date Associated with Specified Activity | | | | | | | | | | | | | | |
|---|---|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| | 1 Oct 2020 | 1 Oct 2021 | 1 Feb 2022 | 1 Apr 2022 | 1 Jul 2022 | 1 Oct 2022 | 3 Feb 2023 | 1 Apr 2023 | 1 Jul 2023 | 1 Oct 2023 | 1 Feb 2024 | 1 Apr 2024 | 1 Oct 2024 | 3 Feb 2025 | 1 Apr 2025 |
| Assumed effective date | x | | | | | | | | | | | | | | |
| Hiring annual goal assessment | | x | | | | x | | | | x | | | | x | |
| Monograph forecast annual posting | | x | | | | x | | | | x | | | | x | |
| TFM Cat I finalization activities complete | | x | | | | | | | | | | | | | |
| Meetings draft guidance issued | | | x | | | | | | | | | | | | |
| Meetings final guidance issued | | | | | | | | | x | | | | | | |
| Public-facing IT dashboard contract awarded | | x | | | | | | | | | | | | | |
| Public-facing IT dashboard functional | | | | | | x | | | | | | | | | |
| IT platform for electronic submission receipt, archiving and reporting: RFP | | | x | | | | | | | | | | | | |
| IT platform: initial contracts awarded | | | | x | | | | | | | | | | | |
| IT platform: business requirements established | | | | | | | | x | | | | | | | |
| IT platform fully functional | | | | | | | | | | | | | | | x |
| Content and format draft guidance issued | | | | x | | | | | | | | | | | |
| Content and format final guidance issued | | | | | | | | | | x | | | | | |
| Consolidated proceedings draft guidance issued | | | | | x | | | | | | | | | | |
| Consolidated proceedings final guidance issued | | | | | | | | | | | x | | | | |

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| Table II.J.3: Summary of Dates of Specified ¹ Activities under OMuFA | | | | | | | | | | | | | | | |
|---|---|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
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| Meeting management TPGs begin | | | | | | x | | | | | | | | | |
| Meeting management TPGs annual goal assessment | | | | | | | | | | x | | | x | | |
| Electronic submission draft guidance issued | | | | | | x | | | | | | | | | |
| Electronic submission final guidance issued | | | | | | | | | | | | X | | | |
| CDER-level dispute resolution updated draft guidance issued | | | | | | | x | | | | | | | | |
| Pre-OMuFA paper document cataloging contract award | | | | | | | x | | | | | | | | |
| Pre-OMuFA paper document cataloging complete | | | | | | | | | | | | | | x | |
| Innovation OMOR TPGs begin | | | | | | | | | | x | | | | | |
| Industry-initiated Specified Safety Change OMORs TPGs begin | | | | | | | | | | x | | | | | |
| Industry-initiated GRASE Finalization OMOR TPGs begin | | | | | | | | | | | | | x | | |
| CDER-level dispute resolution TPGs begin | | | | | | | | | | x | | | | | |
| Solid oral dosage forms proposed administrative order and draft guidance issued | | | | | | | | | | | | | | | x |

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| Abbreviations: ANPR = Advance Notice of Proposed Rulemaking; CAT = category; CDER = Center for Drug Evaluation and Research; COU = monograph conditions of use; GRASE = generally recognized as safe and effective; IT = information technology; OMOR = Over-the-Counter Monograph Order Request; OMUFA = Over-the-Counter Monograph User Fee Act; TFM = Tentative Final Monograph; TPGs = timelines and performance goals 1: These are not all the activities that the FDA monograph review staff will be engaged in, but only those for which goal dates are specified under OMUFA. FDA will continue its many baseline monograph activities, such as: addressing ongoing and emerging safety issues; carrying out mandated activities under the Sunscreen Innovation Act and an antiseptic consent decree; training; and numerous other activities described elsewhere in this goals document | | | | | | | | | | | | | | | |